

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC.,)
)

Plaintiff,)
)

vs.)
)

Civil Action No. 06-164-SLR

APOTEX INC. and APOTEX CORP.,)
)

Defendants.)
)
)
)

**PLAINTIFF'S REPLY IN FURTHER SUPPORT OF ITS MOTION TO
STRIKE APOTEX'S AFFIRMATIVE DEFENSE OF UNENFORCEABILITY,
DISMISS APOTEX'S COUNTERCLAIM OF UNENFORCEABILITY
AND STRIKE APOTEX'S AFFIRMATIVE DEFENSE OF MISUSE**

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**INTRODUCTION AND
SUMMARY OF THE ARGUMENT**

Subsequent to Plaintiff MedPointe Healthcare Inc. ("MedPointe") filing its Motion to Strike Apotex's Jury Demand, Strike Apotex's Affirmative Defense of Unenforceability, Dismiss Apotex's Counterclaim of Unenforceability, and Strike Apotex's Affirmative Defense of Misuse ("Motion") (D.I. 16), Apotex withdrew its jury demand, and MedPointe withdrew the portion of its Motion seeking to strike Apotex's jury demand. The Court entered a Stipulated Order (D.I. 25) to this effect, thereby removing any dispute over Apotex's jury demand.

MedPointe respectfully submits this Reply in further support of the remaining portions of its Motion. Specifically, MedPointe respectfully requests that the Court strike Apotex's affirmative defense of unenforceability, dismiss Apotex's counterclaim of unenforceability, and strike Apotex's affirmative defense of misuse.

As set forth in MedPointe's Opening Brief (D.I. 17) and as further explained in this Reply, defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") failed to *plead* their affirmative defense and counterclaim of unenforceability with the specificity required by the Federal Rules of Civil Procedure and failed to *plead* a legally cognizable patent misuse defense. In its Answering Brief (D.I. 20), Apotex improperly attempts to bolster its deficient pleadings with attorney argument. It is well settled, however, that in determining whether to dismiss a counterclaim under Rule 12(b)(6) or strike a defense under Rule 12(f), a court must consider the sufficiency of the allegations contained in the *pleadings alone*. See, e.g., *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 185 & n.6 (3d Cir. 2001); *Environ Products, Inc. v. Total Containment, Inc.*, 951 F. Supp. 57, 60 (E.D. Pa. 1996).

As pled, Apotex's unenforceability defense, unenforceability counterclaim and misuse defense are deficient. Accordingly, Apotex's affirmative defense of unenforceability should be stricken, its counterclaim of unenforceability dismissed, and its affirmative defense of misuse stricken.

ARGUMENT

I. Apotex's Unenforceability Defense Should Be Stricken And Its Unenforceability Counterclaim Dismissed

Apotex's unenforceability defense (D.I. 11, Fourth Defense ¶¶ 31-33) and unenforceability counterclaim (D.I. 11, Count IV ¶¶ 58-64) are premised on allegations of inequitable conduct. As Apotex acknowledges in its Answering Brief at page 5, these allegations of inequitable conduct are subject to the heightened pleading requirements of Fed. R. Civ. P. 9(b), which require that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). *See also Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Systems, LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003).

Enforcement of the heightened pleading requirement of Rule 9(b) is designed to weed out baseless allegations of inequitable conduct. Inequitable conduct is not, and should not be, "a magic incantation to be asserted against every patentee." *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987). As the Federal Circuit has noted, "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague." *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). Indeed, "an unsupported charge of 'inequitable conduct in the Patent Office' is a negative contribution to the rightful administration of justice." *Id.* Allegations of inequitable conduct must be pled with particularity at the time they are made – whether as part of an initial pleading or an amended

pleading under Fed. R. Civ. P. 15 – because, when determining whether to dismiss a counterclaim under Rule 12(b)(6) or strike a defense under Rule 12(f), a court must consider the sufficiency of the allegations contained in the pleadings alone. *See, e.g., Hutchins*, 253 F.3d at 185 & n.6 ("It is black-letter law that '[a] motion to dismiss for failure to state [a] claim under Federal Rule [of] Civil Procedure 12(b)(6) is to be evaluated only on the pleadings.'" (quoting *Mahone v. Addicks Utility Dist. of Harris County*, 836 F.2d 921, 935 (5th Cir. 1988))); *Environ*, 951 F. Supp. at 60 ("The decision to strike an affirmative defense is based on the pleadings alone.").

Unsupported allegations of inequitable conduct cannot be made in an attempt to justify discovery on this issue. *See Samsung Electronics Co., Ltd. v. Texas Instruments Inc.*, No. 3:96-CV-0001-P, 1996 WL 343330, at *3 (N.D. Tex. April 18, 1996) ("A general allegation of inequitable conduct should not be used as a launching pad for extensive or unwarranted discovery, and holding Plaintiff to the strictures of Rule 9(b) may assist in discouraging that practice."). Sufficient facts must be pled at the time the inequitable conduct allegation is made that "specify the time, place, and content of any alleged misrepresentations made to the PTO or otherwise 'give the defendant[] notice of the precise misconduct alleged.'" *Agere Sys. Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 733-34 (D. Del. 2002) (citations omitted). *See also EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261 (D. Del. 1996) (a party alleging inequitable conduct must provide "notice of the precise misconduct alleged"); *McKesson Information Solutions, LLC v. The Trizetto Group, Inc.*, No. 04-1258-SLR, 2005 U.S. Dist. LEXIS 6733, at *7 (D. Del. Apr. 20, 2005) (party alleging unenforceability due to inequitable conduct "must plead with particularity those facts which support the claim the patent holder acted fraudulently before the PTO"). If discovery is required before a claim or defense of

inequitable conduct can be properly pled, the claim or defense should not be pled and, instead, leave to file an amended pleading pursuant to Fed. R. Civ. P. 15 should be sought in the future if warranted. Consistent with this procedure, this Court will set a deadline by which the parties can move to amend the pleadings. *See* this Court's form Scheduling Order (patent), ¶ 3, revised January 2006.¹

As explained in further detail below, Apotex's unenforceability counterclaim and affirmative defense, as pled, fail to satisfy the requirements of Rule 9(b). Accordingly, Apotex's unenforceability counterclaim should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6) and its unenforceability counterclaim stricken pursuant to Fed. R. Civ. P. 12(f).

Apotex's unenforceability defense is pled in three paragraphs of its Answer (D.I. 11, ¶¶ 31-33), and the same allegations are repeated in Apotex's unenforceability counterclaim (D.I. 11, ¶¶ 59-61). The first paragraph of Apotex's unenforceability defense, ¶ 31, which corresponds to ¶ 59 of its unenforceability counterclaim, states:

31. The '194 patent is unenforceable as procured through inequitable conduct. In violation of their duty of candor to the United States Patent & Trademark Office ("PTO"), applicants for the '194 patent misled the PTO about the properties of the alleged invention claimed therein. More particularly, circumstances constituting the applicants' inequitable conduct include, but are not limited to affirmative misrepresentation regarding the benefits of azelastine administered as a nasal spray.

This paragraph does not itself "specify the time, place, and content of any alleged misrepresentations made to the PTO or otherwise 'give [] notice of the precise misconduct alleged.'" *Agere*, 190 F. Supp. 2d at 734. As such, it contains only conclusory allegations of inequitable conduct that fail to satisfy Rule 9(b).

¹ The proposed Order that MedPointe submitted in connection with this Motion does not seek to dispose of Apotex's deficient counterclaim and defenses with prejudice. Apotex can later seek leave to amend its Answer if it obtains facts during discovery which allow it to satisfy Rule 9(b).

The second paragraph of Apotex's unenforceability defense, ¶ 32, which corresponds to ¶ 60 of its unenforceability counterclaim, states:

32. The '194 patent asserts that the surprising feature of the invention is that the azelastine formulations of the '194 patent cause neither somnolence nor the bitter taste side effects of previous azelastine formulations. However, bitter taste is a well known side-effect of azelastine intranasal spray, as disclosed in, for example, *Curr. Med. Res. Opin.* (1997), Volume 14, No. 1, pp 21. MedPointe admits in its product insert for Astelin[®] brand azelastine nasal spray (attached as Exhibit A) indicates that major side effects include bitter taste (19.7% of individuals), somnolence (11.5% of individuals) and fatigue (2.3% of individuals).

The '194 patent issued in 1992, from a U.S. patent application that was filed with the PTO in 1988. The only two documents cited by Apotex in support of this allegation – an article bearing on its face a 1997 copyright date and an Astelin[®] Nasal Spray package insert bearing on its face a revision date of May 2003 – post-date the issue date of the patent. These documents do not, and cannot, support a claim of inequitable conduct *during* the prosecution of the '194 patent, as they did not even exist at that time. Even Apotex concedes that the cited references are not "demonstrative of applicant's knowledge during the prosecution of the '194 patent." Answering Br. at 6.

Inequitable conduct based on an alleged misrepresentation requires "actual knowledge of falsity or an obligation to know it." *Jaskiewicz v. Mossinghoff*, 822 F.2d 1053, 1058 (Fed. Cir. 1987). Failing to identify any factual support from the relevant time – *before* the '194 patent issued – in support of these allegations, Apotex's allegations in ¶ 32 fall short of the requirements of Rule 9(b). To allow Apotex's unsupported allegations to stand would make the protections of Rule 9(b) meaningless, as this would allow a patent challenger to evade the heightened pleading requirements in every case by generally alleging that a representation to the PTO was untrue.

Apotex's argument that the Court should overlook the deficiencies of the allegations in ¶ 32 because "discovery in this case is yet to begin" is without merit. *See* Answering Br. at 6. The sufficiency of the allegations contained in the pleadings alone are considered when evaluating a motion to dismiss a counterclaim under Rule 12(b)(6) or strike a defense under Rule 12(f). *See, e.g., Hutchins*, 253 F.3d at 185 & n.6. Moreover, Apotex can seek leave to amend its Answer if it later discovers any facts to support its baseless allegations.

The third and final paragraph of its unenforceability defense, ¶ 33, which corresponds to ¶ 61 of its unenforceability counterclaim, states:

33. Also, during prosecution, the applicants argued, as an indicium of non-obviousness, that azelastine more effectively inhibited liberation of histamine compared with the prior art, the compound of Example 1 of United States Patent No. 4,704,387 even though Example 4 was closer to azelastine. *A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support and further evidentiary support that such acts were done with the intent to mislead the PTO and to fraudulently extend patent protection of azelastine.*

(emphasis added). Without citing to any factual support, Apotex makes the assertion that Example 4 of United States Patent No. 4,704,387 ("the '387 patent") is closer to azelastine than Example 1 of the same patent. In its Answering Brief, Apotex goes further, alleging that the applicants for the '194 patent compared azelastine "to a prior art compound it [*sic*] knew was not the closest prior art to azelastine." Answering Br. at 7. This is what Apotex now argues; it is not what Apotex pled. Apotex's unenforceability allegation contains no factual support regarding how or why Example 4 may be closer to azelastine than Example 1, let alone how or why the applicants for the '194 patent should have known that.

Failing to identify any factual support *whatsoever*, Apotex's allegations in ¶ 33 fall short of the requirements of Rule 9(b). To allow Apotex's unsupported allegations to stand would make the protections of Rule 9(b) meaningless, as this would allow a patent challenger to

evade the heightened pleading requirements in every case by simply alleging that the applicant should have shared the challenger's subjective view of the prior art.

Apotex's unenforceability contentions are not pled with the specificity required by the Federal Rules of Civil Procedure. As a result, its unenforceability defense should be stricken and its unenforceability counterclaim dismissed.

II. Apotex's Misuse Defense Should Be Stricken, As It Fails As A Matter Of Law

A court deciding whether to grant a Rule 12(f) motion to strike a defense looks only to the sufficiency of the pleadings. *Environ*, 951 F. Supp. at 60 ("The decision to strike an affirmative defense is based on the pleadings alone"). After construing the facts, as pled, in favor of the nonmoving party, a court properly grants a motion to strike when "it appears to a certainty that . . . [the movant] would succeed despite any state of the facts, which could be proved in support of the defense." *McKesson*, 2005 U.S. Dist. LEXIS 6733, at *3. *See also France Telecom S.A. v. Novell, Inc.*, No. 102-437-GMS, 2002 WL 31355255, at *1 (D. Del. Oct. 17, 2002) (motion to strike will be denied only "if the defense is sufficient under the law"). As discussed in MedPointe's Opening Brief, and further explained below, Apotex's misuse defense, as pled, fails as a matter of law.

Apotex's misuse defense is pled in one paragraph of its Answer (D.I. 11, ¶ 34), which states:

34. The '194 patent is invalid and obtained fraudulently and by inequitable conduct. MedPointe submitted the '194 patent to the FDA to be listed among Approved Drug Products With Therapeutic Equivalence Evaluation (also known as the "Orange Book") as covering azelastine hydrochloride. MedPointe also has commenced this infringement action against Apotex. MedPointe's efforts to enforce the '194 patent, by infringement suits and by listing that patent in the Orange Book, constitute patent misuse.

As pled, Apotex's misuse defense is premised on two actions by MedPointe: (1) enforcement of the '194 patent; and (2) listing the '194 patent in the Orange Book. Neither of these actions, however, constitutes patent misuse.

**A. MedPointe's Commencement Of This Action
Cannot Constitute Patent Misuse**

The only factual allegation that Apotex made regarding MedPointe's enforcement of its patent rights is that MedPointe "commenced this infringement action against Apotex." This factual allegation is not in dispute. But as explained in MedPointe's Opening Brief, the mere commencement of an infringement action is excluded from misuse by 35 U.S.C. § 271(d)(3). Indeed, "given the specific exceptions to patent misuse provided by Congress, *defendant must plead more than a conclusory allegation of patent misuse* in order to provide fair notice of the nature of the defense." *Advanced Cardiovascular Systems, Inc. v. Scimed Sys., Inc.*, No. C-96-0950 DLJ, 1996 U.S. Dist. LEXIS 11702, at *10 (N.D. Cal. July 24, 1996) (emphasis added).

In an apparent attempt to circumvent § 271(d)(3), Apotex goes further in its Opposition Brief at page 10, arguing that its misuse defense is not premised on MedPointe's commencement of litigation alone, but on "bad faith enforcement of a patent [MedPointe] knew or should have known was invalid or unenforceable." Again, this is what Apotex now argues; it is not what Apotex *pled*. In its Answer, Apotex failed to allege any improper conduct whatsoever. As such, Apotex's misuse allegation is distinguishable from those in both *McKesson* and *Hoffman-La Roche*, where the defendant actually made allegations of improper conduct in their pleadings. *McKesson*, 2005 U.S. Dist. LEXIS 6733, at *4; *Hoffman-La Roche Inc. v. Genpharm Inc.*, 50 F. Supp. 2d 367, 379 (D.N.J. 1999).

Apotex cannot succeed in proving patent misuse under any set of facts it pled regarding MedPointe's commencement of this action. Apotex's patent misuse defense should be stricken.

B. MedPointe's Submission Of The '194 Patent For Listing In The Orange Book Cannot Constitute Patent Misuse

The only factual allegation that Apotex made in its Answer regarding the listing of the '194 patent in the Orange Book is that "MedPointe submitted the '194 patent to the FDA to be listed among Approved Drug Products With Therapeutic Equivalence Evaluation (also known as the "Orange Book") as covering azelastine hydrochloride." While MedPointe disputes certain aspects of this allegation that are irrelevant to this Motion, it admits that information regarding the '194 patent was submitted to the FDA for listing in the Orange Book in connection with Astelin® (azelastine hydrochloride) Nasal Spray. But even when this Orange Book listing allegation is construed in favor of Apotex, it fails to support an affirmative defense of patent misuse.

In its Answering Brief at pages 11-12, Apotex attempts to recast its straightforward Orange Book listing allegation into one of listing "with full knowledge of [] invalidity and/or unenforceability, thereby illegally restraining trade by prohibiting competition" and/or "bad faith enforcement." But that is not what Apotex *pled*. Apotex made no assertion of bad faith or improper purpose in its misuse allegation. Nor did Apotex assert that MedPointe made a false representation to the FDA in connection with the listing of the '194 patent. As such, Apotex's Orange Book listing allegation, as a matter of law, cannot constitute patent misuse and should be stricken. *See Astra Aktiebolag v. Kremers Urban Dev. Co.*, Nos. 99 Civ. 8928 (BSJ), 99 Civ. 9888 (BSJ), 2001 U.S. Dist. LEXIS 23879, at *2-*3 (S.D.N.Y. Oct. 26, 2001).

In *Astra*, the court struck misuse defenses and dismissed misuse counterclaims where the defendant alleged only that these patents had been listed in the Orange Book and asserted against the defendant. *Id.* at *2. The *Astra* court further noted that both alleged actions "can be entirely legal and appropriate actions taken by a patent-holder." *Id.* at *2. The court allowed a misuse claim to remain pending as to a fourth patent because the defendant had alleged that the patentee submitted false information to the FDA in connection with the listing of that patent in the Orange Book. *Id.* at *3.

As set forth in MedPointe's Opening Brief, Apotex's Orange Book listing allegation, as pled, attempts to impugn activity that is protected by the *Noerr-Pennington* doctrine. Moreover, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), which created 21 U.S.C. § 355(j)(5)(C)(ii)(I), established the procedure for a party seeking to challenge the propriety of an Orange Book listing. If a patent does not claim the drug or approved method for using the drug for which it is listed, an ANDA applicant "may assert a counterclaim seeking an order requiring the [patent] holder to correct or delete the patent information." *Id.*

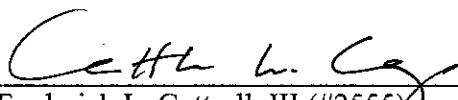
Apotex cannot succeed in proving patent misuse under any set of facts it pled regarding the listing of the '194 patent in the Orange Book. Accordingly, its Orange Book listing allegation is insufficient under Rule 12(f) to support a defense of patent misuse, and should be stricken.

CONCLUSION

For all these reasons, MedPointe respectfully requests that the Court strike Apotex's affirmative defense of unenforceability, dismiss Apotex's counterclaim of unenforceability, and strike Apotex's affirmative defense of misuse.

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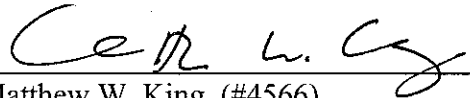
CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 1, 2006, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing, and hand delivered to the following:

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